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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,871	02/09/2006	Iden Mossanen-Shams	15892.15	2365

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EXAMINER	
NATNITHITHADHA, NAVIN	

ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,871	MOSSANEN-SHAMS, IDEN	
	Examiner	Art Unit	
	NAVIN NATNITHITHADHA	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10, 12-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10 and 12-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 February 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 October 2008 has been entered.

Response to Amendment

2. According to the Amendment, filed 10 October 2008, the status of the claims is as follows:

Claims 10 and 19 are currently amended;

Claims 12-18 and 20-26 are previously presented; and

Claims 1-9 and 11 are cancelled.

Response to Arguments

3. Applicant's arguments, see Remarks, pp. 6-8, filed 10 October 2008, with respect to the rejection of claims 10, 12, 15, 19, 21, and 24 under 35 U.S.C. 102(b) as being anticipated by Reiten, U.S. Patent No. 5,191,893 A ("Reiten"), have been fully considered, but are moot in view of the new ground(s) of rejection.

4. Applicant's arguments, see Remarks, pp. 8-10, filed 10 October 2008, with respect to the rejection of claims 13, 14, 22, and 23 under 35 U.S.C. 103(a) as being anticipated by Reiten in view of Wright, U.S. Patent No. 4,559,953 A ("Wright"), have been fully considered, but are moot in view of the new ground(s) of rejection.

5. Applicant's arguments, see Remarks, pp. 10-11, filed 10 October 2008, with respect to the rejection of claims 16, 17, 25, and 26 under 35 U.S.C. 103(a) as being anticipated by Reiten in view of Sackner et al, U.S. Patent No. 5,159,935 A ("Sackner"), have been fully considered, but are moot in view of the new ground(s) of rejection.

6. Applicant's arguments, see Remarks, pp. 10-11, filed 10 October 2008, with respect to the rejection of claims 16, 17, 25, and 26 under 35 U.S.C. 103(a) as being anticipated by Reiten in view of Sackner et al, U.S. Patent No. 5,159,935 A ("Sackner"), have been fully considered, but are moot in view of the new ground(s) of rejection.

7. Applicant did not respond to the rejection of claims 18 and 20 under 35 U.S.C. 103(a) as being unpatentable over Reiten. However, the prior rejection to these claims is rendered moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 10, 12, 15, 18-21, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiten in view of Coyle et al, U.S. Patent No. 7,267,652 B2 ("Coyle").

In reference to claims 10 and 19:

Reiten teaches a volume variation sensor for monitoring obstructive sleep apnea, which comprises an elongated tubular enclosure with a thin deformable wall (Abstract). The tubular sensor is wrapped around the patient's chest (Fig. 1) for following body movements caused by the user's lung operation (Col. 5, lines 17-30). A sensor is used for sensing fluctuations in a user's lung operation (Col. 3, lines 1-10). The sensor is attached to a pressure monitoring apparatus (14) for determining successive values representative of the user's lung fluctuations and for translating values into appropriate lung-evaluating information (the device is capable of detecting sleep apnea based on the change in the volume and pressure inside the tubular belt, Col. 2, lines 40-46). The belt comprises at least one chamber (21 and 15) formed between an inner wall (The side near element 10) and at least one an outer wall (Fig. 3, the opposite side of 10).

The chamber has a substantially enclosed volume of gas disposed therein (Col. 3, lines 21-33). The chamber is sized and shaped so as to span the entire lung region of the user's body (Fig. 1). The inner wall follows the displacement of the entire lung region (Fig. 5). The inner wall and the outer wall combine to compress the volume of gas as the inner wall is pushed towards the outer wall during inspiration as the lungs expand and to decompress the volume of gas as the inner wall relaxes during expiration as the lungs contract (Col. 5, lines 17-30). The sensor is directly exposed to the enclosed volume for sensing changes in pressure within the chamber throughout inspiration and expiration (the pressure monitoring aperture is connected to the chamber 15 via tube 13).

Reiner does not teach "said item comprising: a front panel corresponding to the user's front; a rear panel corresponding to the user's back; an upper aperture sized and shaped to allow the user's head to be outside the item when worn; a lower aperture sized and shaped to allow the user's legs to be outside the item when worn; said front panel extending from said upper aperture to said lower aperture and being sized and shaped to substantially entirely cover the anterior chest wall and at least the upper abdomen".

However, Coyle teaches a pulmonary volume evaluation device (Abstract) comprising: an item ("garment") 1 worn over the user's body for following body movements caused by the user's lung operation, said item 1 comprising: front and rear panels (Fig. 1 and Col. 5, lines 19-35); an upper aperture sized and shaped to allow the user's head to be outside the item when worn (Fig. 1); a lower aperture sized and

shaped to allow the user's legs to be outside the item when worn (Fig. 1); and said front panel extending from said upper aperture to said lower aperture and being sized and shaped to substantially entirely cover the anterior chest wall and at least the upper abdomen (Fig. 1); an inner wall and an outer wall (Fig. 1). It would have been obvious for one of ordinary skill in the art to modify Reiner's sensor to be placed in Coyle's garment because Coyle provides the following suggestion to the combination:

> Although respiratory inductive plethysmography (RIP) is the preferred measurement technology, the systems and methods of this invention are *readily adapted to other sensor technologies*. *Such sensors technologies include, for example*, body impedance sensors; mercury-containing silastic strain gauges, *bellows pneumographs*, *volume pneumographs*, differential linear transformers, inductive transducers of body circumference, magnetometers sensing body diameters, piezoelectric transducers measuring local movements, movement analysis by optical reflection, and so forth.

In reference to claims 12 and 21:

Reiten teaches a seal (Fig. 4, the airtight chamber 15 is sealed) for sealing the chamber (the chamber 15) is connected to the tube 13 which is connected to the pressure aperture 14, and the chamber 15 is airtight, the aperture will detect the changes in pressure inside the chamber in order to determine sleep apnea, Col. 3, lines 2-6 and Col. 5, lines 17-30).

In reference to claims 15 and 24:

Reiten teaches the item comprises a front panel (the front of the belt, including the buckle) and a rear panel (the rest of the belt), where the chamber is disposed in the rear panel (Fig. 1).

In reference to claims 18 and 20:

Reiten in view of Coyle teaches all of the claim limitations; see the rejection of claims 10 and 19 above.

However, Reiten in view of Coyle fails to explicitly teach that: a feedback means or means for capturing and evaluating comprises at least one of: a microprocessor, a computer, and a data logger. Reiten discloses that the pressure measurement registered by the pressure apparatus (14 of Reiten) can be displayed and used in order to determine sleep apnea in a patient (Fig. 6A). Even though Reiten fails to explicitly teach the use of a processor or computer for generating these graphs, it is inherent that a processing means must have been used in order to save and present the collected pressure values by each sensor (11 and 12 of Reiten). In any event, Coyle teaches such devices in Figure 1.

9. Claims 13, 14, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiten in view Coyle, as applied to claims 10 and 19 above, and further in view of Wright.

In reference to claims 13, 14, 22, and 23:

Reiten in view of Coyle teaches all of the claim limitations; see the rejection of claims 10 and 19 above.

However, Reiten in view of Coyle fails to teach that: the inner wall is substantially resilient and the outer wall is substantially rigid in relation to the inner wall. The inner wall may follow, in use, the movement caused by the user's lung operation whilst the

outer wall remains substantially rigid. Wright teaches: an apparatus is used for detecting and measuring changes in the shape of a wall of a chamber. The device includes a detector capsule adapted for attachment to the wall and pneumatically connected to a volume transducer responsive to changes in the internal volume produced by changes in the shape of the wall (Abstract of Wright). The capsule (1 of Wright) comprises a cup shaped rigid body (2 of Wright), which may be made of metal or any suitable rigid plastic material which is closed by a resiliently deformable material (diaphragm 3 of Wright). The diaphragm may be any plastic material such as polyurethane (Col. 1, lines 59-68 and Col. 2, lines 28-44 of Wright). It would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have replaced the tubular chamber of Reiten with a capsule and a transducer similar to the one taught by Wright in order to monitor respiration activities in neonates or adults, as has been explicitly taught by Wright (Col. 1, lines 10-13). Substituting one known element with another element would have yielded predictable results.

10. Claims 16, 17, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coyle in view of Reiten, as applied to claims 10 and 19 above, and further in view of Sackner.

In reference to claims 16 and 25:

Reiten in view of Coyle teaches all of the claim limitations; see the rejection of claims 10 and 19 above.

Reiten also discloses that other known devices are used for monitoring the volume changes along the torso of a subject, including impedance pneumography and inductive plethysmography which are expensive methods and may also pick up unwanted signals such as cardiac events (Col. 1, lines 40-45 of Reiten). Reiten also teaches using two belts for monitoring the chest and abdominal volume displacement within the patient's body (Fig. 1 of Reiten).

However, Reiten in view of Coyl fails to teach that: at least one chamber comprises two chambers each of which correspond to a lung and that each chamber is positioned over a separate lung when the item is worn over the body of the user.

Sackner teaches: a non-invasive estimation of individual lung function (Abstract of Sackner), which comprises transducers (12 and 14 of Sackner) that are placed on different sections of the torso in order to measure the changes of the volume of the underlying lungs (Abstract and Fig. 1A of Sackner). As disclosed in Figs. 12A, 12C, 13A and 13B the inductive transducers can be placed at different locations on the patient's body in order to monitor each lung separately.

As disclosed by Reiten in order to reduce the cost and reduce the error in monitoring volume displacement within the patient's lung, one can replace the inductive transducers with the tubular belt of Reiten (Col. 1, lines 40-68 of Reiten). Therefore, it would have been obvious to one having ordinary skill in the art at time the applicant's invention was made to have replaced the multiple transducers of Sackner (as disclosed in Figs. 12A, 12C, 13A and 13B of Sackner) with the air tube belt of Reiten in order to

monitor the respiration of the patient to study sleep apnea and to also be able to monitor each lung separately.

In reference to claims 17 and 26:

Reiten in view of Coyle teaches all of the claim limitations; see the rejection of claims 10 and 19 above.

Reiten also discloses that other known devices are used for monitoring the volume changes along the torso of a subject, including impedance pneumography and inductive plethysmography which are expensive methods and may also pick up unwanted signals such as cardiac events (Col. 1, lines 40-45 of Reiten). Reiten also teaches using two belts for monitoring the chest and abdominal volume displacement within the patient's body (Fig. 1 of Reiten).

However, Reiten in view of Coyle fails to teach that: at least one chamber comprises four chambers each of which correspond to one of an upper rib region and a lower rib region of a lung. The four chambers configured so that two of the four chambers are respectively positioned over an upper rib region and a lower rib region of a lung, and the other two of the four chambers are respectively positioned over an upper rib region and a lower rib region of the other lung when the item is worn over the body of the user.

Sackner teaches: a non-invasive estimation of individual lung function (Abstract of Sackner), which comprises transducers (12 and 14 of Sackner) that are placed on different sections of the torso in order to measure the changes of the volume of the underlying lungs (Abstract and Fig. 1A of Sackner). As disclosed in Figs. 12A, 12C,

13A and 13B the inductive transducers can be placed at different locations on the patient's body in order to monitor each lung separately.

As disclosed by Reiten in order to reduce the cost and reduce the error in monitoring volume displacement within the patient's lung, one can replace the inductive transducers with the tubular belt of Reiten (Col. 1, lines 40-68 of Reiten). Therefore, it would have been obvious to one having ordinary skill in the art at time the applicant's invention was made to have replaced the multiple transducers of Sackner (as disclosed in Figs. 12A, 12C, 13A and 13B of Sackner) with the air tube belt of Reiten in order to monitor the respiration of the patient to study sleep apnea and to also be able to monitor each lung separately.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The other patents cited in the PTO-892 teach subject matter related to the Applicant's claims. The Examiner suggests reviewing these patents before responding to the present Office Action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Navin Natnithithadha/
Patent Examiner, Art Unit 3735
12/30/2008